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26 **UNITED STATES DISTRICT COURT**

27 **DISTRICT OF NEVADA**

28 PHARMA TECH SOLUTIONS, INC. and
DECISION IT CORP.,

Plaintiffs,

v.

LIFESCAN, INC., LIFESCAN SCOTLAND,
LTD. and JOHNSON AND JOHNSON

Defendants.

Case No.: 2:16-cv-00564-RFB-PAL

**PLAINTIFFS' OPPOSITION TO
DEFENDANTS' MOTION TO DISMISS
THE COMPLAINT UNDER RULE 12(b)(6)**

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1 **I. INTRODUCTION**

2 The Complaint filed by Plaintiffs Pharma Tech Solutions, Inc. (“Pharma Tech”) and Decision
 3 IT Corp. (“Decision IT”) (collectively “Plaintiffs”) adequately alleges patent infringement and easily
 4 satisfies Rule 12(b)(6). In addition to specifically alleging infringement, the Complaint encloses two
 5 claim charts – spanning almost 40 pages – that specifically outline how the asserted patents are
 6 infringed by the One Touch Ultra test strips and meters (“Accused Products”) sold by Defendants
 7 Lifescan, Inc., Lifescan Scotland, Ltd. and Johnson & Johnson (collectively “Lifescan”). As the
 8 adequacy of a claim is evaluated by looking at the four corners of the pleadings, this should end the
 9 analysis. Plaintiffs’ allegations are not, however, the focus of Lifescan’s Motion to Dismiss the
 10 Complaint Pursuant to Rule 12(b)(6) (“Motion”). Dkt. No. 34.

11 While Lifescan’s Motion is denominated a pleadings challenge, in reality it is anything but a
 12 challenge to the Complaint on its face. Instead of arguing that the allegations in the Complaint are
 13 somehow deficient, the Motion attempts to contravene them with attorney argument and extrinsic
 14 evidence. Indeed, Lifescan attempts to bolster its pleadings challenge with substantive declarations.
 15 At the same time, Lifescan asks this Court to dismiss Plaintiffs’ Complaint on a motion to dismiss on
 16 the theory that this Court can somehow decide infringement as a matter of law without considering
 17 any evidence for any of this external material. This is, of course, totally unprecedented and wrong.

18 As set forth in Plaintiffs’ concurrently-filed Objections to Request for Judicial Notice, which
 19 is incorporated herein, Lifescan’s evidence is not subject to judicial notice. However, Lifescan’s
 20 Motion would fail even if all of Lifescan’s unsupported evidentiary submissions were judicially
 21 noticed by this Court and considered for what they supposedly represent. In fact, Lifescan’s
 22 uncorroborated evidentiary presentation simply does not disprove the averments in the Complaint.

23 Plaintiffs are entitled to discovery on their well-pled claims. Lifescan’s frantic efforts to
 24 avoid discovery, including by filing a fatally-flawed pleadings challenge based on external evidence
 25 and by issuing numerous ultimatums demanding that Plaintiffs immediately dismiss their lawsuit or
 26 face reprisals and liability for attorneys’ fees, strongly suggest that Lifescan desperately fears what
 27 discovery may uncover. Lifescan’s Motion should be denied and the parties should be allowed to
 28 commence discovery.

1 **II. BACKGROUND**

2 **A. The History Between the Parties and How Lifescan uses the Court System to**
 3 **Quash a Competitor**

4 This is not the first lawsuit between Pharma Tech and Lifescan. In and around 2011, Pharma
 5 Tech was part of a group that developed a superior, affordable glucose test strip known as
 6 “GenStrip.” The GenStrip was cleared for sale in the United States by the FDA on November 30,
 7 2012. The GenStrip is compatible with Lifescan’s One Touch Ultra line of meters and, at the time,
 8 the only third-party strip cleared by the FDA for use in Lifescan’s meters. Lifescan’s One Touch
 9 Ultra line of meters and test strips comprises more than 30% of the market for glucose test systems
 10 in the United States and provides Lifescan with hundreds of millions of dollars in revenue annually.
 11 The GenStrip threatened Lifescan’s monopoly in the market for test strips compatible with its
 12 meters.

13 In lieu of competing, Lifescan cynically turned to the court system to thwart GenStrip sales
 14 and drown Pharma Tech in legal fees. In 2011, fifteen months prior to the GenStrip even being
 15 cleared for sale by the FDA, Lifescan brought a patent infringement action in the Northern District
 16 of California against Pharma Tech and others relating to the GenStrip. Among other asserted
 17 patents, Lifescan’s lawsuit was amended in 2012 to allege that the GenStrip infringed U.S. Patent
 18 No. 7,250,105 (the “‘105 patent”). In 2013, Lifescan obtained an order from the District Court
 19 preliminary enjoining GenStrip sales. That injunction was, however, soon stayed by the Federal
 20 Circuit pending the appeal and later reversed in a published opinion, which held that Lifescan’s
 21 rights in and to the ‘105 patent were exhausted. *LifeScan Scotland, Ltd. v. Shasta Techs., LLC*, 734
 22 F.3d 1361 (Fed. Cir. 2013). The ‘105 patent was thereafter ruled to be invalid upon an *inter parties*
 23 *review* by the U.S.P.T.O., and that ruling was upheld by the Federal Circuit in a *per curiam* decision
 24 issued earlier this year. *Lifescan Scotland, Ltd. v. Pharma Tech Solutions, Inc.*, 633 Fed.Appx. 789
 25 (Fed. Cir. 2016). Ultimately, Pharma Tech achieved what was essentially a complete defense verdict
 26 in the Northern District of California action when the parties entered into a settlement to dismiss all
 27 claims and *Lifescan agreed to pay Pharma Tech money. See Declaration of John Shaeffer*
 28 (“Shaeffer Decl.”), Ex. A.

1 Lifescan's lawyers successfully spoiled the launch of the GenStrip and forced Pharma Tech
 2 to incur substantial legal fees, even if their legal tactics were eventually rejected by the courts. The
 3 imposition of the wrongfully-entered (and later vacated) preliminary injunction kept GenStrip off the
 4 market for months and wounded the product for years thereafter. Further, Lifescan's lawyers also
 5 salted the earth to wrongfully deprive Pharma Tech of an opportunity to properly develop a market
 6 after the injunction was lifted. During the short pendency of the preliminary injunction against
 7 GenStrip sales, Lifescan's lawyers misappropriated Pharma Tech's customer list, which was
 8 designated as "Attorneys' Eyes Only" under a protective order. Lifescan's lawyers violated the
 9 express terms of the protective order by using that information to send letters to Pharma Tech's
 10 distribution and reseller customers as well as the customers of Pharma Tech's distribution and
 11 reseller customers, including a large subset of the nation's 14,000-plus independent pharmacies.
 12 These letters contained threats of legal action if the recipient continued to do business with Pharma
 13 Tech. The district court found that Lifescan's lawyers violated a court order, sanctioned Lifescan for
 14 more than \$40,000,¹ and eventually dismissed Lifescan's lawsuit in its entirety. Sadly, the harm to
 15 Pharma Tech, and the stigma placed on the GenStrip product, could not be undone.

16 *Apropos* of nothing whatsoever, Lifescan references in its Motion a "Safety Communication"
 17 from the FDA that concerns the GenStrip. This is simply a transparent attempt by Lifescan to
 18 inflame prejudices and divert attention from Plaintiffs' Complaint, which of course is the focus of a
 19 Rule 12(b)(6) pleadings challenge. Lifescan's Motion, however, fails to acknowledge that this letter
 20 related to a record-keeping issue that was not under the control of Plaintiffs, and that it was issued
 21 long-after Lifescan's attorneys has been sanctioned for threatening Pharma Tech's distributor and
 22 retailer partners. In any event, Lifescan has no claim to the high ground in light of the facts that
 23 Lifescan's own products have been the subject of numerous recalls,² Lifescan has settled, for tens of
 24 millions of dollars, claims that it overcharged Medicare³ and Lifescan has pled guilty to crimes and
 25 paid a \$60 million fine for selling defective equipment to patients (because of which three diabetics

26 ¹ See Shaeffer Declaration, Ex. B.

27 ² E.g., February 2010 recall of test strips (www.fda.gov/Safety/Recalls/ucm202119.htm); March
 2013 recall of meters (www.fda.gov/medicaldevices/safety/listofrecalls/ucm349127.htm).

28 ³ See [www.justice.gov/sites/default/files/civil/legacy/2014/04/18/LifeScan,
 %20%20et%20al.%202000.pdf](http://www.justice.gov/sites/default/files/civil/legacy/2014/04/18/LifeScan,%20%20et%20al.%202000.pdf).

allegedly died).⁴ Lifescan's accusations of bad behavior, unrelated to any claim or defense in this lawsuit, should be taken with an enormous grain of salt.

B. This Lawsuit

The Complaint alleges that Lifescan's One Touch Ultra blood glucose test strips and meters infringe U.S. Patent Nos. 6,153,069 (the "'069 patent") and 6,413,411 (the "'411 patent") (collectively, the "Patents-in-Suit"). The Patents-in-Suit are directed to a novel approach for testing the amount of glucose in the blood. Briefly, the Patents-in-Suit claim a system in which two "Cottrell currents" are read, converted into an analyte concentration and compared to determine if they are within a prescribed range with one another. This invention results in more accurate glucose readings.

Plaintiff's Complaint attaches copies of the Patents-in-Suit (Exs. A and B) as well as charts (Exs. C and D) that graphically depict the manner in which the Accused Products practice each of the limitations of at least one claim of each of the Patents-in-Suit. The claim charts include nearly 40-pages worth of analysis concerning infringement and easily satisfy the pleading standard for pleading patent infringement, whatever that might be. *Cf. Hologram USA, Inc. v. Pulse Evolution Corp.*, 2016 WL 199417, *2 n. 1 (D. Nev. Jan. 15, 2016) (citing advisory note and holding that notice pleading established prior to *Iqbal/Twombly* is sufficient even after removal of Form 18 from the Federal Rules of Civil Procedure) and *Tannerite Sports, LLC v. Jerent Enterprises, LLC*, 2016 WL 1737740, at *4 (D. Or. May 2, 2016) (recent removal of Form 18 from Rules requires application of heightened pleading standard identified in *Iqbal/Twombly*).

III. LEGAL STANDARD

A. Limited Factual Averments Required to State a Claim

When evaluating a Rule 12(b)(6) motion, a court must accept as true all allegations of material facts that are in the complaint and must construe all inferences in the light most favorable to the nonmoving party. *Moyo v. Gomez*, 32 F.3d 1382, 1384 (9th Cir. 1994). "Specific legal theories need not be pleaded so long as sufficient factual averments show that the claimant may be entitled to some relief." *Fontana v. Haskin*, 262 F.3d 871, 877 (9th Cir. 2001).

⁴ See www.nytimes.com/2000/12/16/business/guilty-plea-by-division-of-drug-giant.html.

1 This plausibility standard is not a probability requirement. *Bell Atlantic Corp. v. Twombly*,
 2 550 U.S. 544 (2007). As the Ninth Circuit held, all that is required in the complaint is a claim that is
 3 plausible on its face. *Sheppard v. David Evans & Assoc.*, 694 F.3d 1045, 1048–49 (9th Cir. 2012).
 4 Rule 8(a)(2) does not require that a complaint contain detailed factual allegations. *Id.* Dismissal of
 5 a complaint for failure to state a claim is not proper where a plaintiff has alleged “enough facts to
 6 state a claim to relief that is plausible on its face.” *Twombly*, 550 U.S. at 570. “A claim has facial
 7 plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable
 8 inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662,
 9 678 (2009).

10 The court is not concerned at this stage with “whether a plaintiff will ultimately prevail” but
 11 whether she can offer evidence to support his claims. *See Mohamed v. Jeppesen Dataplan, Inc.*, 579
 12 F.3d 943, 960 (9th Cir. 2009), *rev'd on other grounds by, Mohamed v. Jeppesen Dataplan, Inc.*, 614
 13 F.3d 1070 (9th Cir. 2010). Further, in reviewing a complaint for purposes of a motion to dismiss,
 14 the plaintiff’s allegations of material fact must be taken as true and construed in the light most
 15 favorable to him. *See Love v. United States*, 915 F.2d 1242, 1245 (9th Cir. 1989). “And, of course,
 16 a well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of those facts
 17 is improbable, and that a recovery is very remote and unlikely.” *Twombly*, 550 U.S. at 556 (internal
 18 quotation omitted).

19 **B. Extrinsic Evidence Cannot be Considered on a Motion to Dismiss**

20 As explained by the Ninth Circuit, on a Rule 12(b)(6) motion to dismiss, extrinsic evidence
 21 cannot be considered on a motion to dismiss:

22 Review is limited to the complaint; “evidence outside the pleadings ... cannot
 23 normally be considered in deciding a 12(b)(6) motion.” “The issue is not whether
 24 a plaintiff will ultimately prevail but whether [plaintiff] is entitled to offer
 25 evidence to support the claims.”

26 *Cervantes v. City of San Diego*, 5 F.3d 1273, 1274-75 (9th Cir. 1993) (*quoting Farr v. United States*,
 27 990 F.2d 451, 454 (9th Cir. 1993) and *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974)); accord *Allen*
 28 *v. United States*, 964 F.Supp.2d 1239, 1251 (D. Nev. 2013) (“Review is limited to the contents of the

complaint.”); *Carstarphen v. Milsner*, 594 F.Supp.2d 1201, 1207 (D. Nev. 2009) (“Review on a motion pursuant to Fed.R.Civ.P. 12(b)(6) is normally limited to the complaint itself. [citation] If the district court relies on materials outside the pleadings in making its ruling, it must treat the motion to dismiss as one for summary judgment and give the non-moving party an opportunity to respond.”); *John Bordynuik Inc. v. JBI, Inc.*, 2015 WL 153439, at *2 (D. Nev. Jan. 13, 2015) (“this motion’s reliance on extrinsic evidence makes dismissal for failure to state a claim inappropriate”).

While courts may take judicial notice of documents referenced in the complaint, courts are not permitted to take judicial notice of any extrinsic facts which are in dispute. *See, e.g., United States v. Corinthian Colleges*, 655 F.3d 984, 999 (9th Cir. 2011) (“As a general rule, we ‘may not consider any material beyond the pleadings in ruling on a Rule 12(b)(6) motion’”; also, noting that the court may take judicial notice of matters in public records, but “we may not, on the basis of evidence outside of the Complaint, take judicial notice of facts favorable to Defendants that could reasonably be disputed”); *Lee v. City of Los Angeles*, 250 F.3d 668, 688 (9th Cir. 2001) (“the district court’s decision to dismiss plaintiffs’ federal claims was rooted in defendants’ factual assertions. In granting defendants’ motions, the court assumed the existence of facts that favor defendants based on evidence outside plaintiffs’ pleadings, took judicial notice of the truth of disputed factual matters, and did not construe plaintiffs’ allegations in the light most favorable to plaintiffs. We therefore ... reverse”) (emphasis added).

Here, Lifescan’s Motion is entirely premised on extrinsic evidence which is in dispute. Given that a Rule 12(b)(6) motion must be limited to the complaint itself, Defendants’ Motion should be denied.

IV. PLAINTIFFS’ CLAIM FOR PATENT INFRINGEMENT IS SUFFICIENTLY PLED

A. The Face of the Complaint Adequately Alleges that the Accused Products Infringe the Patents-in-Suit

There is little dispute but that the allegations of the Complaint, on their face, are more than adequate to plead infringement. The Complaint asserts that “Defendants’ One Touch Ultra blood glucose test strips and meters infringed at least Claim 1 of the ‘069 Patent and Claim 4 of the ‘411 Patent. Complaint, ¶¶ 13-14. The Complaint attaches charts that include almost 40 pages of

analysis outlining how accused products infringe the asserted claims. *Id.*, Ex. C, D. As set forth in the attached charts, the Accused Products measure blood glucose twice and then compare the results in a manner that infringes the Patents-in-Suit. Lifescan, not surprisingly, disagrees. Lifescan argues that the Accused Products take two measurements of electric currents and compare the currents. Motion at 7:17-27. Lifescan argues that the Accused Products do not take two blood glucose measurements. *Id.*

Lifescan concedes, as it must, that Plaintiffs' pled that the Accused Products operate in an infringing manner. Motion at 2:18-26. Lifescan also acknowledges that Plaintiffs' Complaint features *evidence* regarding infringement in the form of a correspondence from one of its own representatives. In that letter, Lifescan's representative notes that:

OneTouch Ultra Test Strip uses patented DoubleSure technology **that automatically conducts two separate glucose measurements on each blood sample for accuracy.** When glucose in a blood sample reacts with the glucose oxidase enzyme in the One Touch Ultra Test Strip, electrons are released and carried by a mediator to two electrodes. The electrodes each measure the flow of electrons separately. **This allows two measurements to be compared and checked, leading to accurate glucose results.** If a significant difference between the two measurements is detected, the OneTouch Meter recognizes there is a problem and an error message is generated.⁵

See Complaint, Ex. C, pg. 14; Ex. D, pg. 15.⁶

Plaintiffs' allegations should be the end of the analysis. *Cervantes*, 5 F.3d at 1274-75. This is even more so as Plaintiffs' allegations are backed by actual evidence of infringement in the form of party admissions. Lifescan disagrees and proffers conflicting evidence, including in the form of

⁵ First instance of emphasis in original, second supplied.

⁶ Lifescan draws a different – and flatly unreasonable – inference from this evidence. Lifescan's Motion asserts that this evidence suggests that the Accused Products *do not* conduct two separate glucose measurements but instead that it takes two measurements of the current generated by the sample. Motion at 11:9-25. However, given that the Complaint must be “construed in the light most favorable to the nonmoving party,” the Court need not select the most reasonable inference. *Faulkner v. ADT Sec. Services, Inc.*, 706 F.3d 1017, 1019 (9th Cir. 2013) (citations omitted).

expert declarations, and discounts the aforementioned admissions as “non-technical.” Motion at 11:21-22. This is, however, a pleadings challenge, not a time for weighing the evidence.

Nevertheless, even at this stage and without any discovery, there is a mountain of other evidence that establishes that the Accused Products operate in an infringing manner – *i.e.*, they take two measurements of blood glucose and compare the results. This evidence, includes, but is certainly not limited to, the representations made by Alex Gorsky, Johnson & Johnson’s Chief Executive Officer.⁷ In a 2009 meeting with investors, Alex Gorsky, who was then Johnson & Johnson’s Worldwide Chairman of the Medical Devices & Diagnostics Group, represented to shareholders that:

The number one patient need regarding blood glucose strips and meters is confidence in the accuracy of the test results. **Lifescan is launching a new blue OneTouch Ultra test strip with double sure technology for accuracy. Double sure technology performs two separate glucose tests with every strip and a self-test to confirm accuracy.** OneTouch Ultra test strips are glucose specific and eliminate the risk of falsely elevated results from other sugars.

Alex Gorsky, Johnson & Johnson’s 3rd Quarter 2009 Earnings Call (October 13, 2009) (emphasis supplied). Plaintiffs are entitled to conduct discovery as to whether Mr. Gorsky’s statements are accurate or, in the alternative, why Johnson & Johnson’s C.E.O. made misrepresentations to its shareholders.

Further, Mr. Gorsky’s description of how the Accused Products operate, and therefore why they infringe the Patents-in-Suit, have been consistently repeated by Lifescan and/or its partners. Attached to the Shaeffer Declaration as Exhibit C is a list of some of the instances in which the Accused Products have been described in the same manner as Mr. Gorsky. While Lifescan filed a pleadings challenge, in accordance with which the focus is supposed to be the four corners of the Complaint, Plaintiffs are prepared to back up their well-founded allegations with substantial

⁷ Defendants Lifescan, Inc. and Lifescan Scotland, Ltd. are wholly owned subsidiaries of Johnson & Johnson.

evidence and are, if necessary, prepared to amend their pleadings to specifically identify each such reference.

B. The References Set forth in Plaintiffs' Complaint Support, Not Contradict, Plaintiffs' Well-Pled Infringement Allegations

The claim charts attached to the Complaint fully support, and plainly do not contradict, Plaintiffs' allegations. Lifescan's Motion relies heavily on a figure taken from its (exhausted, invalid) '105 patent, Table 1, which Lifescan represents reads on the Accused Products. However, as set forth in the concurrently-filed Declaration of Dr. Joseph Wang, Distinguished Professor in the Department of Nanoengineering at the University of California at San Diego ("Wang Decl."), Table 1 proves that the Accused Products *do* practice the Patents-in-Suit.

The claims of the '069 patent and the '411 patent are directed to an apparatus and method, respectively, in which the current generated by a sample is measured at least two different times. The Patents-in-Suit both refer to the "Cottrell equation," which predicts how the current generated by a sample will change over time. Wang Decl., ¶ 7. In electrochemistry, the Cottrell equation describes current decay as proportional to the reciprocal of the square root of time in a controlled potential experiment. Wang Decl., ¶ 8. The Cottrell equation predicts the decay pattern of a current generated by reactants in a diffusion-controlled (diffusion-limited) reaction. *Id.* The current decays as a linear function of the inverse of the square root of time ($1/t^{1/2}$). *Id.* Thus, to determine whether the current generated by a given reaction obeys the Cottrell equation, the current versus $1/t^{1/2}$ is graphed. *Id.* If a reaction obeys the Cottrell equation, one would expect that a plot of current versus $1/t^{1/2}$ would generate a straight line. *Id.*

As reflected in the diagram that is set forth in both Patents-in-Suit as Figure 7, the measured current will decrease at a predictable rate over the course of time.

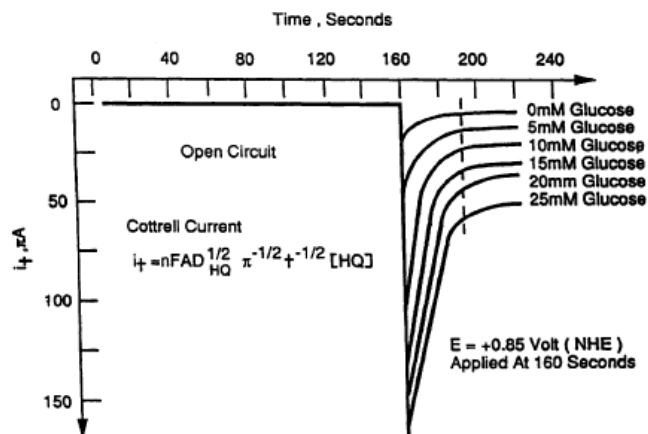


FIG. 7

The change in current as predicted by the Cottrell equation can be used to verify the accuracy of the test. Wang Decl. ¶ 10. In other words, current can be measured at two different times to determine whether the electrical current readings are as predicted by the equation. *Id.* Figure 11 of the '069 patent reflects electrical current readings that do, and do not, operate in the predicted manner. *Id.*

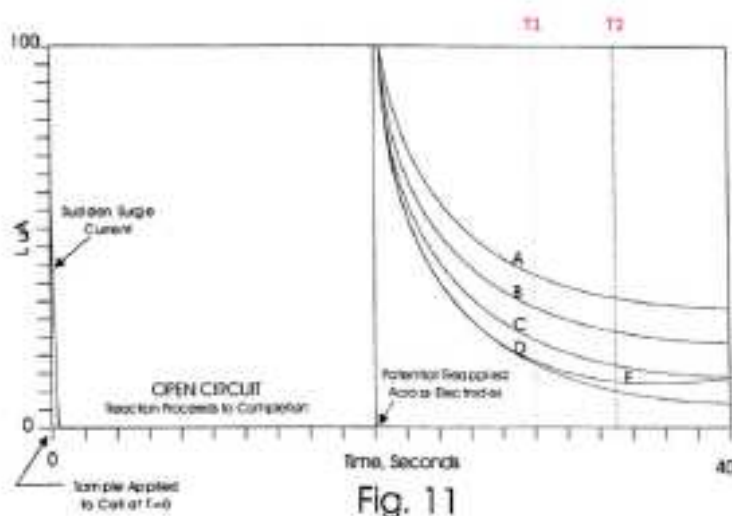


Fig. 11

The electrical readings from samples A, B, C, and D all are consistent with the results predicted by the Cottrell equation. *Id.* The results from sample E, however, are not. *Id.* This discrepancy suggests that there was a testing error and that the results should be disregarded. *Id.*

Current readings are essential to testing for blood glucose because there is a fixed relationship between those readings and glucose concentration. Wang Decl., ¶ 11. Higher levels of current demonstrate higher levels of glucose. *Id.* The following is Figure 6 in both Patents-in-Suit that reflects the proportionality between glucose concentration and Cottrell currents where the test is conducted 30 seconds after the application of the potential (*see* '069 patent, Col. 11, Lns. 35-37):

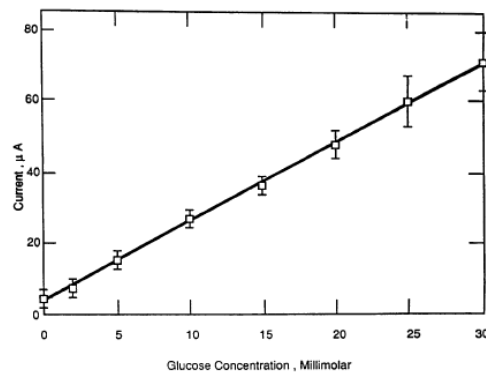


FIG. 6

The Patents-in-Suit describe converting at least two current readings to an analyte and comparing the results “to confirm that they are within a prescribed percentage of each other.” ‘069 patent, Claim 1 and ‘411 patent, Claim 1. This is reflected in Figure 12 of the ‘069 patent:

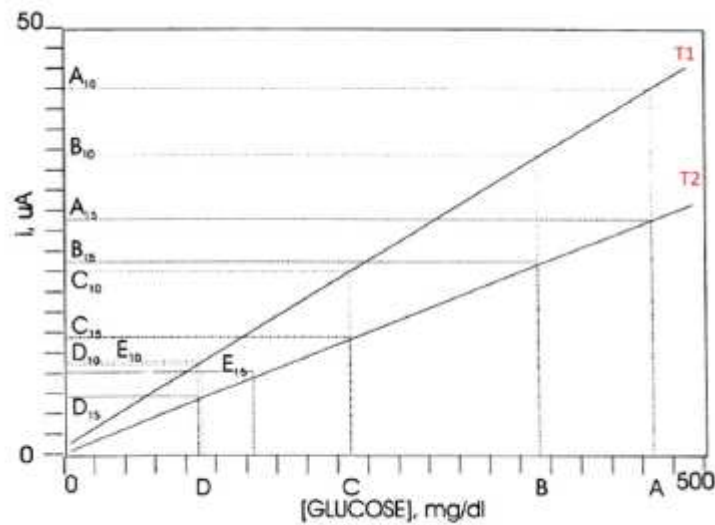


Fig. 12

In Figure 12, the current readings from the samples (A through E) are graphed against glucose readings. Wang Decl., ¶ 13. Currents for each sample have been tested twice and both tests for each sample are plotted along the current scale on the left. *Id.* A10 reflects the current reading in the A sample at 10 seconds and A15 reflects the current reading in the A sample at 15 seconds, *etc.* *Id.* The straight lines that are pointed upwards reflect the proportionality between current and glucose levels depending on the number of seconds after the application of the potential. *Id.* The lines above have been marked T1 and T2 to reflect their corresponding timing. The top line (T1) reflects proportionality after 10 seconds and the lower line (T2) after 15. *Id.* Samples A through D achieved the expected results. Wang Decl., ¶ 14. The tests performed on these samples at different times resulted in the same glucose measurement. *Id.* However, the tests on sample E resulted in disparate results, suggesting that the test was a failure and cannot be relied upon by patient or doctor. *Id.*

Critically, the Patents-in-Suit describe – but are certainly not limited to – test strips with one working electrode. Wang Decl., ¶ 15. The Patents-in-Suit describe a process whereby multiple readings are taken from the single electrode and compared. *Id.* Neither the claims nor the specifications, however, preclude the Patents-in-Suit from reading on test strips with multiple electrodes. *Id.*

Table 1 reflects the fact that the Accused Product takes a current reading from a sample and converts that reading to analyte. Wang Decl., ¶ 16. That step, among others, is claimed by both the Patents-in-Suit.

TABLE 1

Volume μL	Working 1: μA	Working 2: μA	% Difference	Error checked	No error check
1	7.07	0.00	-706800		7.07
1	6.94	5.98	-16.2175732		12.92
1	5.53	0.01	-92050		5.54
1	6.99	7.09	1.42393909	14.09	14.09
1	7.34	7.02	-4.59016393	14.35	14.35
1	7.16	6.79	-5.49742078	13.94	13.94
1	7.01	3.47	-102.13441		10.48
1	7.07	5.69	-24.2578605		12.77
1.2	7.18	4.54	-58.2286847		11.72
1.2	7.00	6.78	-3.35055351	13.78	13.78
1.2	7.09	1.79	-297.032475		8.88
1.2	6.31	0.00	-157550		6.31
1.2	6.78	6.79	0.11788977	13.56	13.56
1.2	6.95	6.59	-5.4029443	13.53	13.53
1.2	6.62	6.28	-5.36795158	12.89	12.89
1.2	7.23	3.78	-91.2721502		11.01
1.4	7.16	6.90	-3.76811594	14.06	14.06
1.4	7.14	6.94	-2.88184438	14.08	14.08
1.4	7.17	7.02	-2.13675214	14.19	14.19
1.4	7.02	6.01	-1.5918958	13.93	13.93
1.4	6.95	6.91	-0.5788712	13.86	13.86
1.4	6.93	6.88	-0.7264419	13.81	13.81
1.4	7.09	6.92	-2.4566474	14.01	14.01
1.4	7.25	7.40	2.02702703	14.65	14.65

Sum of current readings used for conversion to analyte concentrations

Source: U.S. Patent 7,250,105.

Per the '105 patent: "In the second half of the test the two currents were first compared. Only if they differed by less than 10% were they then added together and put forward as valid results." Col. 5, lns. 46-48.

Lifescan disingenuously infers from the information set forth in Table 1 that products that practice the '105 patent, like the Accused Products, could not infringe. Lifescan misleadingly notes that, according to Table 1, two currents are measured from two separate working electrodes ("Working 1" and "Working 2"), compared, and then added together. Lifescan argues that this is the comparison between two samples required by the Patents-in-Suit, except that, in the Accused Products, the comparison is performed of the currents prior to the conversion to analyte and therefore the Accused Products do not infringe.

Lifescan's arguments are pure smoke and mirrors.

Plaintiffs do not rely on Table 1 for the proposition that the Accused Products compare two analyte readings. Rather, as set forth in Plaintiffs' charts, Table 1 establishes that the Accused Products perform an electrical current reading and convert that reading into analyte, as required by the Patents-in-Suit. Wang Decl. ¶ 18. Other evidence, including but not limited to the customer

1 service email set forth in Plaintiffs' charts and the admission made by Lifescan's C.E.O., establishes
2 that the Accused Products do this at least twice and compare the result. *Id.* The fact that Table 1
3 also suggests that the current itself is tested prior to being converted to analyte is an additional step
4 that is not excluded by the claims and does not take the Accused Product outside the scope of
5 infringement. *Id.*

6 Courts routinely refuse to even entertain arguments like those proffered by Lifescan. Nearly
7 identical arguments were presented – and rejected – in *Delavau, LLC v. Corbion NV*, 2016 WL
8 3410176 (D.N.J. June 16, 2016). In that case, the defendant moved under Rule 12(b)(6) and argued
9 that exhibits attached to the complaint undermined allegations set forth in the complaint. The court
10 denied the motion on the grounds that it was not empowered to resolve factual disputes at the
11 pleadings stage. It held:

12 When considering a motion to dismiss, the Court must ask whether plaintiff is
13 entitled to offer evidence to support its claim, and not whether plaintiff will
14 ultimately prevail. Defendants argue that the exhibits to the complaint show that
15 they have not and cannot directly infringe plaintiff's patent . . . In contrast,
16 plaintiff argues that the exhibits to the complaint show that defendants . . .
17 infringe plaintiff's patent. If defendants' interpretation of the exhibits to
18 plaintiff's complaint is correct, plaintiff may not ultimately prevail on its direct
19 infringement claim. The Court, however, cannot credit defendants' interpretation
20 of the exhibits over plaintiff's conflicting interpretation at this motion to dismiss
21 stage. Consequently, plaintiff's direct infringement claim may proceed. *Id.*

22 Similarly, in *Hologram USA*, 2016 WL 199417, *3, Chief Judge Navarro denied a Rule
23 12(b)(6) motion to dismiss an infringement claim. In so doing, C.J. Navarro rejected the defendants'
24 argument that an attachment to the complaint disproved infringement and warranted dismissal:

25 Though Defendants do not dispute that Plaintiffs have pled all of the necessary
26 components of a patent infringement claim, they nonetheless argue that the Court
27 should grant their Motion to Dismiss because a diagram attached to the SAC
28 definitively shows that [Defendants] did not infringe the '519 patent. However,

1 with this argument, Defendants seek to enforce a standard which borders upon
 2 that of summary judgment, far exceeding the pleading standard for a patent
 3 infringement claim. . . . [T]he Court is unwilling to rely solely on this diagram,
 4 which was published prior to discovery, in resolving the complex factual
 5 questions raised by Plaintiffs' claims. Accordingly, the Court finds Defendants'
 6 request to be premature, and the instant Motion will be denied. *Id.*
 7 *See also Max Sound Corporation v. Google, Inc.*, 2015 WL 2251060, *3-*4 (N.D. Cal. 2015)
 8 (denying Rule 12(b)(6) motion to dismiss that was based on statements made by patentee during the
 9 prosecution of the patent-in-suit and holding that the court "declines to take judicial notice of
 10 Defendants' interpretation of the [prosecution history]. A Rule 12(b)(6) motion is not the proper
 11 vehicle to examine and interpret the prosecution history."').⁸

12 **C. Lifescan's External Evidence Should Not be Considered and, in Any Event, this**
 13 **Evidence Does Not Contravene Express Allegations in the Complaint**

14 Lifescan also attempts to contravene Plaintiffs' allegations by drawing outlandish inferences
 15 from material that is entirely outside of the pleadings. This material is not appropriate for a
 16 pleadings challenge and in any event does not actually contradict the averments set forth in
 17 Plaintiffs' Complaint. There are two primary pieces of external "evidence" relied upon by Lifescan
 18 in its Motion: (1) a 2012 declaration from Dr. Mark Meyeroff and (2) a 2016 declaration from Allan
 19 MacRae. In each instance, Lifescan offers the external "evidence" as proof of the statements set
 20 forth therein and for the purposes of contravening the allegations set forth in Plaintiffs' Complaint.
 21 Lifescan's arguments lack merit.

22 First, Lifescan offers a declaration from Dr. Meyeroff, one of the experts that Lifescan
 23 retained in the Northern District of California lawsuit that has since been dismissed. Motion at Ex.
 24 3. The Motion argues that, in a declaration that was filed in that case in 2012, Dr. Meyeroff asserted

25 ⁸ Lifescan's Motion misleadingly asserts that Plaintiffs "admitted that [they] cannot rely on the
 26 doctrine of equivalents here," citing to letter from Plaintiffs' counsel that was attached as Exhibit 6
 27 to Lifescan's Motion. Motion at 21:12-13 (citing Ex. 6 at 3 n. 3). However, as set forth in that
 28 letter, Plaintiffs noted only that Lifescan's literal infringement is so plain that Plaintiffs would not
 need to rely upon the doctrine of equivalents to oppose any motion to dismiss. Motion, Ex. 6, at 3
 n.3. While Plaintiffs currently have no plans to pursue infringement under the doctrine of
 equivalence, they specifically reserve the right to assert that theory in this litigation at a later date.

1 that the Accused Products compare “currents.” Motion at 12:11-13:2, Ex. 3 at ¶¶ 39-40. Lifescan
 2 continues by asserting that Pharma Tech “did not dispute this” in the prior litigation and asks the
 3 Court to assume, as a matter of law, that the statements set forth in the declaration are true. *Id.* at
 4 12:19.

5 Second, Lifescan’s Motion attaches a 2016 declaration from Allan MacRae, one of its
 6 software engineers. Motion at Ex. 10. The Motion argues that, after Plaintiffs filed their
 7 Complaint, Lifescan provided Plaintiffs with a copy of an “algorithm” in accordance with which the
 8 Accused Products operate. Motion at 13:4-14:8. The Motion cites to Mr. MacRae’s declaration as
 9 evidence that the algorithm supposedly disproves infringement.

10 Without reference to any authority, Lifescan’s Motion asserts that these declarations can
 11 invalidate assertions set forth in Plaintiffs’ Complaint for the purposes of Rule 12(b)(6). Of course,
 12 this is utter nonsense.

13 This “evidence” has no place whatsoever in a pleadings challenge. Lifescan’s Motion is
 14 tellingly devoid of any authority that courts can infer from a party’s *silence, in another litigation*,
 15 that a particular fact is true and serves to invalidate well-pled allegations to the contrary for the
 16 purposes of deciding a Rule 12(b)(6) motion. Yet, this is precisely what Lifescan asks this Court to
 17 do when considering Dr. Meyeroff’s declaration. Further, Lifescan failed to reference any authority
 18 suggesting that courts can use the unexamined declaration from the defendant’s employees to
 19 dismiss a complaint under Rule 12(b)(6), as Lifescan would have the Court do with Mr. MacRae’s
 20 declaration.

21 As set forth above, courts refuse to accept as true statements that are set forth in documents
 22 *that are attached to the complaint* where they conflict with a Plaintiffs’ allegations. *Delavau*, 2016
 23 WL 3410176; *Hologram USA*, 2016 WL 199417, *3. Here, Lifescan asks the Court to accept as true
 24 argumentative declarations from its own expert and from one of its employees. *A fortiori*, this
 25 external material cannot be used to contravene pleading allegations under Rule 12(b)(6). *See also*
 26 *M/V Am. Queen v. San Diego Marine Constr. Corp.*, 708 F.2d 1483, 1491 (9th Cir. 1983) (“a court
 27 may not take judicial notice of proceedings or records in another cause so as to supply, without
 28 formal introduction of evidence, facts essential to support a contention in a cause then before it”);

1 *Lee v. City of Los Angeles*, 250 F.3d 668, 688 (9th Cir. 2001) (“On a motion to dismiss pursuant to
 2 Federal Rule of Civil Procedure 12(b)(6), the Court must limit its review to the four corners of the
 3 operative complaint, and may not consider facts presented in briefs or extrinsic evidence.”); *Arpin v.*
 4 *Santa Clara Valley Transp. Agency*, 261 F.3d 912, 925 (9th Cir. 2001) (“evidence outside the
 5 complaint” is “extraneous evidence [that] should not be considered in ruling on a motion to
 6 dismiss.”).

7 Finally, the Accused Products infringe the Patents-in-Suit irrespective of whether they
 8 compare currents as argued by Dr. Meyeroff and Mr. MacRae. As set forth above, Plaintiffs have
 9 alleged, and have presented evidence to establish, that the Accused Products convert at least two
 10 current readings to analyte and compare the analyte. Lifescan’s focus on the ability to also compare
 11 currents is a red herring. Wang Decl., ¶ 19.

12 **D. Lifescan’s Motion Requires Claim Construction and Should be Rejected on that**
 13 **Basis Alone**

14 Lifescan’s Motion requires the Court to construe certain terms before assessing the merits of
 15 Lifescan’s non-infringement evidence. The Motion proposes constructions for “analyte” and for
 16 “concentration.” Specifically, the Motion proposes that the Court construe “analyte” to mean “a
 17 component that is being measured in a chemical analysis,” based on the definition set forth in the
 18 McGraw-Hill Dictionary of Scientific and Technical Terms. Motion at 6:5-9, 17, n. 11. The Motion
 19 proposes that the Court construe the term “concentration” to mean the “relative content of a
 20 component . . . expressed in a percentage by weight or by volume,” based on the definition set forth
 21 in Webster’s Third New International Dictionary, 2002. *Id.* at 17, n. 10. With these constructions,
 22 Lifescan argues that the Accused Product does not infringe.

23 This case is not, of course, currently positioned for claim construction proceedings. Indeed,
 24 the Federal Circuit has held that claim construction should not be done at the pleading stage at all.
 25 *In re Bill of Lading Transmission & Processing Sys. Patent Litig.*, 681 F.3d 1323, 1343 n. 13 (Fed.
 26 Cir. 2012) (explaining that it would be “inappropriate” for a district court to engage in “claim
 27 construction at the pleading stage—with no claim construction processes undertaken.”). A number
 28 of courts have held that a motion to dismiss should be denied if it requires the court to construe the

meaning of claims and perform an infringement analysis since this is improper at the pleading stage. *See e.g., Anglex Tech, LLC v. NuVasive, Inc.*, 2014 WL 197736, *2 (S.D. Cal. Jan. 14, 2014); *Fujitsu Ltd. v. Belkin, Int'l., Inc.*, 782 F.Supp.2d at 868, 890 (N.D. Cal. 2011); *Eon Corp. IP Holdings LLC v. FLO TV Inc.*, 802 F.Supp.2d 527, 534 n. 7 (D. Del. 2011); *Actus, LLC v. Bank of Am. Corp.*, 2010 WL 547183, at *2 (E.D. Tex. Feb. 10, 2010); *Yangaroo, Inc. v. Destiny Media Techs. Inc.*, 2009 WL 2836643, at *3 (E.D. Wis. Aug. 31, 2009).

Lifescan's Motion asks the Court to assume the meaning for two claim terms in conjunction with its analysis of whether the Accused Products infringe. Putting aside the fact that pleadings challenges do not depend on whether the allegations will ultimately be proven true, Lifescan's Motion "inappropriate[ly]" requires "claim construction at the pleading stage" and should be denied on that basis. *In re Bill of Lading*, 681 F.3d at 1343 n. 13.

V. IN THE ALTERNATIVE, PLAINTIFFS SHOULD BE GRANTED LEAVE TO AMEND

If the Court believes that the Complaint does not state a claim under Rule 12(b)(6), it should grant Plaintiffs leave to replead. "It is black-letter law that a district court must give plaintiffs at least one chance to amend a deficient complaint, absent a clear showing that amendment would be futile." *Nat'l Council of La Raza v. Cegavske*, 800 F.3d 1032, 1041 (9th Cir. 2015).

VI. CONCLUSION

For the foregoing reasons, Lifescan's Motion should be denied. Alternatively, if the Court believes that any of Plaintiffs' claims are legally insufficient, the Court should provide Plaintiffs with leave to amend their pleading and supplement their existing allegations at this time.⁹

Dated: September 1, 2016

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⁹ Plaintiffs reserve the right to seek fees and costs in this case in accordance with 35 U.S.C. § 285 and *Octane Fitness, LLC v. Icon Health & Fitness, Inc.*, 134 S.Ct. 1749 (2014).